

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 02, 2023

Terns Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39926
(Commission File Number)

98-1448275
(IRS Employer
Identification No.)

1065 East Hillsdale Blvd.
Suite 100
Foster City, California
(Address of Principal Executive Offices)

94404
(Zip Code)

Registrant's Telephone Number, Including Area Code: (650) 525-5535

N/A

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value per share	TERN	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On March 2, 2023, Terns Pharmaceuticals, Inc. (the “Company”) issued a press release providing a business update on the Company’s programs. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit No.	Description
99.1	Press Release issued by Terns Pharmaceuticals, Inc. on March 2, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TERNS PHARMACEUTICALS, INC.

Date: March 2, 2023

By: /s/ Bryan Yoon

Bryan Yoon

Chief Operating Officer & General Counsel



Terns Pharmaceuticals Provides Program Updates and Announces Participation at Upcoming March Investor Conferences

Completes enrollment in Phase 2a DUET clinical trial of TERN-501 (THR- β agonist) as a treatment for NASH with top-line results expected in third quarter of 2023

On track to initiate U.S. clinical trial for TERN-701 (allosteric BCR-ABL inhibitor) in CML in second half of 2023; enrollment progress update from ongoing China Phase 1 trial expected at a major upcoming oncology conference

IND-enabling activities for TERN-601 (oral GLP-1R agonist) ongoing; on track to initiate first-in-human clinical trial in obesity in second half of 2023

Cash and cash equivalents expected to provide runway into 2026

FOSTER CITY, Calif., March 2, 2023 (GLOBE NEWSWIRE) -- Terns Pharmaceuticals, Inc. ("Terns" or the "Company") (Nasdaq: TERN), a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology, non-alcoholic steatohepatitis (NASH) and obesity, today announced that management will participate in three upcoming investor conferences in March 2023 and provided program updates across the Company's development programs as outlined below.

"We are delighted to have completed enrollment in the Phase 2a DUET trial of TERN-501 and express our gratitude to the people participating in this trial. We would also like to recognize the excellence of the study investigators and the Terns team in recruiting the trial. This milestone takes us one step closer to bringing TERN-501, our THR- β agonist with potentially class-leading efficacy, safety and tolerability profiles, to people living with NASH. With top-line data expected in the third quarter of this year, our team is expeditiously preparing for a potential initiation of a Phase 2b/3 clinical program in 2024," said Erin Quirk, M.D., president, head of research and development of Terns. "We are also eagerly looking forward to a Type C meeting in May 2023, which was granted by the U.S. FDA to discuss the opportunity to leverage non-invasive endpoints to support NASH product development and, potentially, for seeking approval for NASH. While we are at the beginning of the journey towards potential pathways to accelerated approval based on non-invasive technologies, we look forward to working with the agency to explore the utility of these exciting technologies with the potential to play an important role in real world settings," added Dr. Quirk.

"I am excited by the continued execution of our team as we strive to bring better medicines to people living with serious diseases," said Sen Sundaram, chief executive officer of Terns Pharmaceuticals. "We expect significant progress across all of our clinical programs in 2023. In addition to NASH, we continue to progress towards initiating both our Phase 1 trial for TERN-701 in CML in the U.S. and our Phase 1 trial for TERN-601 for obesity in the second half of 2023, positioning us for three significant clinical readouts across our three lead programs by the end of 2024."

Program Updates

TERN-701: Oral, allosteric BCR-ABL tyrosine kinase inhibitor (TKI) for chronic myeloid leukemia (CML)

- Terns expects to initiate a clinical trial for TERN-701 in the United States in the second half of 2023, with potential top-line readouts from initial dose-escalation cohorts in 2024
 - The Phase 1 trial for TERN-701 is expected to include sites from Europe and other Terns territories, in addition to the United States
 - Terns has initiated production of TERN-701 drug supply in support of the planned Phase 1 trial initiation in the second half of 2023
- A trial-in-progress (TiP) abstract has been submitted to an upcoming major oncology conference and summarizes the ongoing Phase 1 study of TERN-701 (HS-10382) in China conducted by Terns' partner Hansoh. The TiP abstract includes an update on enrollment progress across dose-escalation cohorts of TERN-701 (HS-10382) administered once daily
 - The Hansoh trial is a dose-escalation and dose-expansion trial (NCT05367700) evaluating the tolerability, efficacy, and pharmacokinetics of TERN-701 (HS-10382) in approximately 100 people with CML in China

TERN-501: Oral, thyroid hormone receptor-beta (THR- β) agonist for NASH

- The Phase 2a DUET trial (NCT05415722), evaluating TERN-501 as a monotherapy and in combination with TERN-101, completed enrollment in February 2023 with top-line data expected in the third quarter of 2023
 - Final enrollment in DUET exceeds 160, increased from the planned enrollment of 140 based on high demand for study participation
 - Primary endpoint is the relative change from baseline in liver fat content as measured by MRI protein density fat fraction (MRI-PDFF) at Week 12 for TERN-501 monotherapy compared with placebo
 - Secondary endpoints include assessment of safety and tolerability, pharmacokinetics, changes in MRI-PDFF and MRI corrected T1 (cT1)
 - DUET is the first clinical trial assessing a THR- β agonist as monotherapy and in combination with an FXR agonist in people with NASH
 - FDA Type C meeting has been scheduled for May 2023
 - Terns plans to explore the opportunity to leverage non-invasive endpoints to facilitate NASH development
 - The Type C meeting, together with data from the ongoing DUET trial, is expected to inform the next stages of clinical development for Terns' NASH program
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- Terns aims to present additional preclinical data to support the dosing of TERN-501 +/- TERN-101 at a scientific conference in the second quarter of 2023
- Drug supply manufacturing is underway, and chronic toxicity data are expected by the third quarter of 2023, to enable the initiation of Phase 2b/3 development following DUET data availability

TERN-601: Oral, small-molecule glucagon-like peptide-1 (GLP-1) receptor agonist for obesity

- Terns' lead GLP-1 receptor agonist program remains on track with the goal of initiating a Phase 1 first-in-human clinical trial in subjects with elevated BMI in the second half of 2023 and with top-line data expected in 2024
 - Terns anticipates completing TERN-601 drug product manufacturing in the first quarter of 2023
- An abstract evaluating food-intake suppression in TERN-601 treated transgenic mice expressing human GLP-1 receptor has been submitted to a major diabetes-focused scientific conference

TERN-800: Oral, small-molecule glucose-dependent insulinotropic polypeptide receptor (GIPR) modulators for obesity

- Lead structural series of GIPR modulators have been identified, with lead optimization efforts underway in 2023
- Candidate nomination and initiation of IND-enabling activities expected in 2024
- GIPR modulators have the potential for combination with GLP-1 receptor agonists, such as TERN-601

Financial Update

Terns' third quarter cash balance as of September 30, 2022, along with \$112 million in December 2022 equity financing proceeds, result in an adjusted cash balance of \$293 million¹, which is expected to provide cash runway into 2026.

Investor Conferences

Members of Terns' senior leadership team will participate at the following upcoming investor conferences in March:

43rd Annual TD Cowen Health Care Conference

Date: March 6-8, 2023

Location: Boston

Format: Leukemia Panel Discussion

Date/Time: Wednesday, March 8th from 12:50 p.m. – 1:50 p.m. ET

Oppenheimer 33rd Annual Healthcare Conference

Date: March 13-15, 2023

Location: Virtual

Format: Company presentation

Date/Time: Tuesday, March 14th from 2:40 p.m. – 3:10 p.m. ET

Evercore ISI NASH Renaissance

Date: March 30, 2023

Location: Virtual

Format: Fireside Discussion

Date/Time: 1:30 p.m. – 1:55 p.m. ET

A live webcast of these events will be available on the investor relations page of the Terns Pharmaceuticals website at <http://ir.ternspharma.com>. A replay of the webcast will be archived on Terns' website for 30 days following the event. The Evercore ISI NASH event webcast link is available from Evercore ISI and will require registration.

About the DUET Trial

The Phase 2a DUET trial (NCT05415722) is a multicenter, randomized, double-blind, placebo-controlled clinical trial in noncirrhotic NASH using a factorial design including both monotherapy and combination arms of TERN-501 and TERN-101. The trial has enrolled over 160 adults with elevated body mass index (BMI \geq 25 kg/m²) and NASH with fibrosis, but not cirrhosis, based on prior liver biopsy and/or imaging and clinical criteria. All participants must have liver fat content measured by magnetic resonance imaging proton density fat fraction (MRI-PDFF) of \geq 10%, MRI corrected T1 (cT1) relaxation time of \geq 800 msec, and meet other inclusion and exclusion criteria. The trial includes a 12-week treatment period and a 4-week follow-up period. The primary endpoint is the relative change from baseline in MRI-PDFF at Week 12 for TERN-501 monotherapy compared with placebo. Secondary endpoints include assessment of changes in MRI-PDFF (combination vs. placebo) and cT1 (TERN-501 monotherapy vs. placebo as well as 501+101 combination vs. placebo). DUET is the first trial assessing a THR- β agonist as monotherapy and in combination with an FXR agonist in people with NASH.

About Terns Pharmaceuticals

Terns Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing a portfolio of small-molecule product candidates to address serious diseases, including oncology, NASH and obesity. Terns' pipeline includes two clinical stage development programs including an allosteric BCR-ABL inhibitor and a THR- β agonist (+/- an FXR agonist), and preclinical small-molecule GLP-1 receptor agonist and GIPR modulator programs. For more information, please visit: www.ternspharma.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements about Terns Pharmaceuticals, Inc. (the “Company,” “we,” “us,” or “our”) within the meaning of the federal securities laws, including those related to the Company’s expectations of timing and potential results of the Company’s clinical trials and other development activities; the potential indications to be targeted by the Company with its small-molecule product candidates; the therapeutic potential of the Company’s small-molecule product candidates; the potential for the mechanisms of action of the Company’s product candidates to be therapeutic targets for their targeted indications; the potential utility and progress of the Company’s product candidates in their targeted indications, including the clinical utility of the data from and the endpoints used in the Company’s clinical trials; the Company’s clinical development plans and activities, including the results of any interactions with regulatory authorities on its programs; the Company’s expectations regarding the profile of its product candidates, including efficacy, tolerability, safety, metabolic stability and pharmacokinetic profile and potential differentiation as compared to other products or product candidates; the Company’s plans for and ability to continue to execute on its current development strategy, including potential combinations involving multiple product candidates; the impact of new legislation and regulatory developments on the Company’s plans for its product candidates, such as the effect of the Inflation Reduction Act of 2022; and the Company’s expectations with regard to its cash runway and sufficiency of its cash resources. All statements other than statements of historical facts contained in this press release, including statements regarding the Company’s strategy, future financial condition, future operations, future trial results, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “aim,” “anticipate,” “assume,” “believe,” “contemplate,” “continue,” “could,” “design,” “due,” “estimate,” “expect,” “goal,” “intend,” “may,” “objective,” “plan,” “positioned,” “potential,” “predict,” “seek,” “should,” “target,” “will,” “would” and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or other comparable terminology. The Company has based these forward-looking statements largely on its current expectations, estimates, forecasts and projections about future events and financial trends that it believes may affect its financial condition, results of operations, business strategy and financial needs. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. These statements are subject to risks and uncertainties that could cause the actual results and the implementation of the Company’s plans to vary materially, including the risks associated with the initiation, cost, timing, progress, results and utility of the Company’s current and future research and development activities and preclinical studies and clinical trials. These risks are not exhaustive. For a detailed discussion of the risk factors that could affect the Company’s actual results, please refer to the risk factors identified in the Company’s SEC reports, including but not limited to its Annual Report on Form 10-K for the year ended December 31, 2021 and its Quarterly Report on Form 10-Q for the periods ended March 31, 2022, June 30, 2022 and September 30, 2022. Except as required by law, the Company undertakes no obligation to update publicly any forward-looking statements for any reason.

Contacts for Terns

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¹ \$187 million of cash, cash equivalents and marketable securities as of September 30, 2022, together with net offering proceeds of \$106 million raised in December 2022
